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Clicking to Health?
A Look at Online Pharmacies, Counterfeit Medicine, and Drug Reimportation

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Abstract

This paper examines the rise of online pharmacies and the issues of drug importation, focusing on the problem of counterfeiting, and reimportation. It describes the positive and negative aspects of online consumer drug purchasing, overviews existing regulation of importation and reimportation, and proposes possible solutions to the problems that arise. In the end, it concludes that individual importation and reimportation should not be allowed, except in very limited circumstances, to continue to safeguard consumer safety.

I. Introduction

In the privacy of their own home, consumers are shopping not only for gifts, clothes, and groceries, but increasingly, pharmaceuticals. As with any internet phenomena, there are numerous advantages and disadvantages arising from empowering people with easy access to products. The rise of internet pharmacies has particularly amplified two important issues – drug importation and reimportation. Among the numerous concerns raised about the importation of drugs manufactured in other countries, is the prevalence of counterfeit medicine, which endangers the public health.¹ Similarly, reimportation, which means the purchasing of drugs that were manufactured in the US and then exported to other countries, carries with it safety concerns.² On the other hand, importation and reimportation allow consumers to purchase medicine they would not otherwise have access to, gives them more say in their health options, and after all, counterfeiting crises in the US have not been as severe as in other countries.³ In addition, there are arguments that reimportation concerns are exaggerated, because the drugs have been manufactured with the protections of the US system.⁴ Thus, finding a path to regulation and enforcement to eradicate the problem is more complex than for some other

¹ See e.g. FDA Finds Consumers Continue to Buy Potentially Risky Drugs Over the Internet, FDA News Release, July 2, 2007, at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108946.htm>. FDA warning consumers about safety concerns of purchasing drugs online, and especially without a prescription. See also Douglas W. Stearn, *Deterring the Importation of Counterfeit Pharmaceutical Products*, 59 FOOD DRUG L.J. 537, 539 (2004). Describing the safety risks to public health from the prevalence of international counterfeiting.

² See Monali J. Bhosle & Rajesh Balkrishnan, *Drug reimportation practices in the United States*, 3(1) THERAPEUTICS AND CLINICAL RISK MANAGEMENT 41, 42 (2007).

³ Michael Veronin, *Packaging and Labeling of Pharmaceutical Products Obtained from the Internet*, 13(1) J. MED. INTERNET RES. e22 (2011), at <http://www.jmir.org/2011/1/e22/>.

⁴ See Niteesh K. Choudhry & Allan S. Detsky, *A Perspective on US Drug Reimportation*, 293(3) J. OF THE AMERICAN MEDICAL ASSOCIATION 358, 359 (2005). Arguing that many drugs reimported from Canada, for instance, are “produced by US manufacturers in FDA approved facilities and are equally safe as drugs consumed currently by Americans.”

illicit or questionable activities, since there are patients who are arguably benefitting from the easier access and lower prices of online drug sales, and who may feel they do not have other options. This paper examines the issues of imported counterfeit medicine and reimportation⁵ as they relate to individual purchasing on the internet, looks at the regulatory responses, and proposes possible steps toward reconciling the opposing views for the benefit of consumers.

II. The Rise of Internet Pharmacies

The high cost of prescription drugs in the United States has severe negative consequences to the health of many Americans. To save money, patients may skip doses or avoid taking the prescribed medication altogether. For instance, one study found that 22% of senior citizens and 32% of the uninsured do not fill their prescriptions because they cannot afford them.⁶ In addition, the recent economic downturn “may have worsened cost-related medication nonadherence, especially among the poorest and the sickest.”⁷ One solution consumers have turned to is to buy medicine from other countries, most commonly with the help of internet pharmacies.⁸ In addition to arguably lower costs, internet pharmacies offer

⁵ While importation and reimportation are discussed separately in some parts of the paper, they are closely related, and the concerns and responses to them are related.

⁶ See Bhosle & Balkrishnan, *supra* note 2, at 41.

⁷ Lana Ivanitskaya et al., *Dirt Cheap and Without Prescription: How Susceptible are Young US Consumers to Purchasing Drugs From Rogue Internet Pharmacies?*, 12(2) J. MED. INTERNET RES. e11 (2010), at <http://www.ncbi.nlm.nih.gov.ezp-prod1.hul.harvard.edu/pmc/articles/PMC2885783/>; see also Vanessa Fuhrmans, *Consumers Cut Health Spending, As Economic Downturn Takes Toll*, WALL ST. J., Sep. 22, 2008, citing a survey by the National Association of Insurance Commissioners, which found that 11% of 686 consumers surveyed were cutting back on prescription drugs to save money.

⁸ See generally Bhosle & Balkrishnan, *supra* note 2. See also Jennifer Cohn, *Prohibitive Cost of HIV/AIDS Therapy in the United States*, 11(7) AMERICAN MEDICAL ASSOCIATION J. OF ETHICS 492, 492-493 (2009). Describing a dilemma faced by a US doctor who prescribed HIV medicine to a patient. The patient told him she could not afford the medicine as it was being sold in regular pharmacies and asked him if it was

other benefits, such as quicker and easier access for “the elderly, infirm, or geographically isolated.”⁹ Also, online pharmacies may have 24-hour pharmacist consultation in different languages, providing an important benefit to patients whose primary language is other than English.¹⁰ While these benefits drive consumer demand for internet drugs, concerns stemming from counterfeit products and drug reimportation continue to grow. Thus, it is important to examine the different structures of internet pharmacies to provide a context for further discussion.

Online pharmacies can be grouped into three general categories. First, there are the “brick and mortar” pharmacies, which resemble closely traditional pharmacies in that they require a prescription from a physician before a consumer can order medicine.¹¹ Within this category, there are pharmacies which are simply online extensions of pharmacy chains (such as Walgreens), and independent pharmacies “which often use the Internet to try to compete with larger chains.”¹²

The second type of pharmacy combines online diagnosis and online drug ordering. Generally, patients fill out a questionnaire about their symptoms and medical history, and a physician reviews their answers, diagnoses the condition, and prescribes the medication.¹³

These types of pharmacies are quick and efficient for consumers – saving them a trip to the

safe to buy the imported generic version of the medicine online “at a fraction of the cost.” The doctor was torn between safety concerns and the immediate problem of having the patient take the medicine.

⁹ Roger Bate, Kimberly Hess, and Robert Brush, *Pilot Study of Internet Drug Availability, Pricing, and Quality*, Research Paper, American Enterprise Institute for Public Policy Research, August 2009, at <http://www.aei.org/docLib/20090820-BateHessBrush.pdf>

¹⁰ See Cohn, *supra* note 8, at 493.

¹¹ See Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*. 28 J. OF LAW, MEDICINE & ETHICS 98 (2000).

¹² Alan M. Weiss, *Buying prescription drugs on the Internet: Promises and pitfalls*. 73(3) CLEVELAND CLINIC J. OF MEDICINE 282, 283 (2006).

¹³ *Id.*

doctor's office, and possibly helping them avoid uncomfortable appointments for embarrassing conditions. However, it is unclear whether consumers actually save money with these transactions, at least on the diagnosis. For instance, one study found that the average cost of the "cyber-doctor" evaluation was more than that of the local office evaluation.¹⁴ Moreover, unlike with traditional pharmacies and their online counterparts, there is a greater concern over the propriety of the credentials of the cyber doctor who is giving out the diagnosis and the prescription, whether the doctor actually resides in the US, and even the question of whether the doctor is real.¹⁵

The third, and most problematic category of online pharmacies, are those that allow consumers to purchase medicine without a prescription. They have been dubbed "rogue" pharmacy sites.¹⁶ FDA warns consumers that these pharmacies "often sell unapproved drugs, drugs that contain the wrong active ingredient, drugs that may contain too much or too little of the active ingredient, or drugs that contain dangerous ingredients."¹⁷ Other major concerns with these pharmacies are patient self-diagnosis and self-medication, which may often lead to overdosing, serious drug interactions, wrong medication for the condition, and other negative consequences that result from removing a reliable practitioner standing between the patient and powerful substances.¹⁸ Another related issue, is that these online outfits often sell

¹⁴ *Id* at 284.

¹⁵ *See id.*

¹⁶ *See e.g.* Importation of Prescription Drugs, Statement of John M. Taylor, III before the Permanent Subcommittee on Investigations Senate Committee on Governmental Affairs [*hereinafter* TAYLOR STATEMENT], July 22, 2004, at <http://www.fda.gov/newsevents/testimony/ucm113635.htm>.

¹⁷ FDA Consumer Health Information, updated Nov. 2010, at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm>.

¹⁸ *See* Isaac D. Montoya & Elda Jano, *Online Pharmacies: Safety and Regulatory Considerations*, 37(2) INT'L J. OF HEALTH SERVICES 279 (2007).

substances that have a high potential for abuse. Reportedly, except for alcohol and tobacco, psychoactive drugs are the second most abused drug in the US (behind marijuana), and rogue pharmacies greatly perpetuate the problem by “permitting uncontrolled dispensing.”¹⁹

There is an attempt to regulate online pharmacies in a variety of ways. State boards of pharmacy regulate online pharmacies by making sure they comply with the state’s licensing requirements, by sending warning letters to pharmacies they believe are operating illegally, by conducting investigations, and by bringing lawsuits against pharmacies, making them face hefty fines.²⁰ Secondly, there is voluntary industry self-regulation. For instance, in 1999, the National Association of Boards of Pharmacy (NABP), an “impartial professional organization that supports the state boards of pharmacy in protecting public health,” created the Verified Internet Pharmacy Practice Sites (VIPPS) program.²¹ Through VIPPS, online pharmacies that meet certain criteria, including compliance with state laws, quality assurance, and safety, get a certification from NABP.²² A search of the NABP website for VIPPS accredited pharmacies as of the writing of this paper has yielded twenty-seven pharmacy sites.²³ In 1999, FDA adopted the Internet Drug Sales Action Plan in response to online drug sales, which outlined a plan to:

- customize and expand the Agency's regulatory and criminal enforcement efforts;
- identify when and with which Federal agencies FDA should partner in joint activities;
- partner with State bodies to address domestic Internet sales;
- engage in public outreach; and,
- provide input to Congress regarding legislation”²⁴

¹⁹ *Id* at 285.

²⁰ See Oliver, *supra* note 11, at 100.

²¹ NABP website at <http://www.nabp.net/about/>, accessed March 15, 2011.

²² See Oliver, *supra* note 11.

²³ NABP website at <http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/>, accessed March 15, 2011.

²⁴ Drug Sales Over the Internet, Statement of Janet Woodcock before the Subcommittee on Oversight and Investigations House Committee on Commerce, July 30, 1999 at <http://www.fda.gov/NewsEvents/Testimony/ucm115047.htm>.

Since then, the Agency has conducted investigations, issued warnings to consumers, and took numerous actions to address illegal online sales.²⁵ In addition to the FDA, other agencies have participated in a response to online drug sales and its related concerns: the Drug Enforcement Agency, Department of Justice, Federal Trade Commission, Department of Health and Human Services, and the US Postal Service.²⁶ However, while regulation may be successful in increasing the quality of legally operating online pharmacies, enforcement is much more difficult in the context of illegal pharmacies, especially those located outside the US.²⁷ In addition to jurisdictional issues, it is very difficult to track the locations of these sites, especially since many of them can shut down and re-open to avoid being detected.²⁸ In these cases, responses “are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the Customs Service to stop the imported drug at a U.S. port-of-entry.”²⁹ Relying on foreign governments to always cooperate with such requests is risky, and

²⁵ See e.g. *FDA Test Results of Prescription Drugs from Bogus Canadian Website Show All Products Are Fake and Substandard*, FDA News Release, July 13, 2004 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108320.htm>; *FDA Announces New Initiative to Protect the U.S. Drug Supply Through the Use Of Radiofrequency Identification Technology*, FDA News Release, Nov. 15, 2004 at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108372.htm>; *FDA Warns About Fraudulent Tamiflu* *Fraudulent product is dangerous to patients allergic to penicillin*, FDA News Release, June 17, 2010, at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm216148.htm>

²⁶ For the list of agencies and a description of their authorities, see Montoya & Jano, *supra* note 18, at 286.

²⁷ See *id* at 286-287. Describing a study by the GAO (General Accounting Office, now the General Accountability Office), which found in 2004 that “despite the regulatory measures against illegally operating sites, they remain operational.”

²⁸ See Jane E. Henney, *Cyberpharmacies and the Role of the US Food And Drug Administration*, 3(1) J. MED. INTERNET. RES. e3 (2001) at

at <http://www.ncbi.nlm.nih.gov.ezp-prod1.hul.harvard.edu/pmc/articles/PMC1761882/>

²⁹ *Id.*

US Customs has its hands full with the “sheer volume of prescription drugs entering the country for individual patients.”³⁰

The bottom line of this survey of the internet pharmacy landscape is that the industry is growing³¹, consumers are flocking to buy online drugs for a variety of reasons, and the trend is wrought with concerns about protecting public health and the integrity of the US drug market.

III. Importation and Reimportation - Overview of the Issues

A. Importation and Counterfeit Medicine

Counterfeit products are a major concern for governments as consumers are fooled and often harmed in their search for a bargain, and for industries whose profits are being cut into and their brands undermined. The concern is especially salient now, as the rise of globalization, paired with easy internet access, has made the counterfeiting market flourish and increased its access worldwide.³² A counterfeit drug, as defined by the Federal Food Drug & Cosmetic Act:

“means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor”³³

³⁰ Palumbo et al., *Policy Implications of Drug Importation*, 29 (12) J. OF CLINICAL THERAPEUTICS, 2758, 2759 (2007).

³¹ See Bate et al., *supra* note 9. Citing a 2009 study by the Deloitte Centre for Health Solutions, which found that 30% of “prescription drug users reported buying drugs online or through the mail in the previous 12 months,” constituting a 9% increase over the 2008 number.

³² See J. Woo, S. Wolfgang, and H. Batista. *The Effect of Globalization of Drug Manufacturing, Production, and Sourcing and Challenges for American Drug Safety*, 83(3) CLINICAL PHARMACOLOGY & THERAPEUTICS 494 (2008).

³³ 21 U.S.C. § 321(g)(2).

Counterfeit drugs are especially worrisome because unlike many other counterfeit products, which copy the look as well as the functionality of the original, they often do not duplicate the actual effects of the drug.³⁴ This strategy makes economic sense for counterfeiters – they can use cheap ingredients, and only focus on mimicking the packaging and appearance of the real medicine, while making a hefty profit.³⁵ The practice means that these fake drugs “often contain the wrong or no active ingredients, or are contaminated by additional toxic chemicals or poor sterilization practices.”³⁶ At best, the fake drugs do not treat the disease, and at worst, they directly cause serious injury and even death.³⁷

Reportedly, the manufacture of counterfeit drugs in the US is rare, due to extensive regulation and vigilant enforcement, and the fake drugs that do make it into the market, seem to come from imports.³⁸ According to the current FDA Commissioner, “nearly 40 percent of the drugs Americans take are imported and nearly 80 percent of the active ingredients in the drugs on the American market come from overseas sources,” which has made the drug supply chain more complex and “mysterious” and has created “new entry points through which

³⁴ See Adam Powell, *Benchmark Legislation: A Measured Approach in the Fight Against Counterfeit Pharmaceuticals*, 61 HASTINGS L.J. 749 (2010).

³⁵ See e.g. William K. Hubbard, *Can the Food and Drug Administration Ensure That Our Pharmaceuticals Are Safely Manufactured?*, 169(18) ARCH. INTERN. MED. 1655, 1656 (2009). Describing how a chemist “substituted oversulfated chondroitin sulfate for true heparin...a dangerous substitute,” most likely because real heparin costs “hundreds of dollars per pound, whereas like amounts of the substitute could be synthesized for less than \$10.” Also noting that “counterfeiters are increasingly turning from fake handbags and currency to drugs because the drugs are so easy to make and sell on world markets,” as reported by the *New York Times*.

³⁶ See Powell, *supra* note 33, at 752.

³⁷ *Id.*

³⁸ *Id.* at 750; see also Veronin, *supra* note 3, for an example of how US drug regulations are more stringent than many other countries: a study found that “of the 41 drug products obtained from online pharmacies from 12 different countries, only 1 product (from Canada) would meet both labeling and packaging guidelines for products dispensed in the United States.”

contaminated, adulterated and counterfeit products can infiltrate the drug supply,” a result which she calls “unacceptable.”³⁹

The FDA’s concern is well-placed, while the exact number of counterfeit drugs in the US is unknown, the general trend seems to be that it is rising. In 1997, FDA’s Office of Criminal Investigations opened nine counterfeit drug cases, while in 2008, it opened fifty-six.⁴⁰ Globally, the Center for Medicines in the Public Interest predicted that counterfeiting would “reach \$75 billion in 2010.”⁴¹ While the World Health Organization (WHO) estimates that less than one percent of drugs “in countries with effective regulatory agencies are likely to be counterfeit,” this does not mean the US should not be worried about these threats.⁴² As an illustration, some of the counterfeiting concerns have included: eighteen million counterfeit tablets of Lipitor recalled in 2003;⁴³ FDA warning in 2007 of twenty-four websites possibly involved in distribution of counterfeit drugs;⁴⁴ in 2010, a warning for a counterfeit diet pill (Alli) on the market and a counterfeit Tamiflu which was being sold online.⁴⁵ While it is already difficult to patrol the drug supply chain, things get more complicated when consumers bypass the regular

³⁹ Remarks as Delivered of Margaret A. Hamburg, M.D. Commissioner of Food and Drugs, Partnership for Safe Medicines Interchange [*hereinafter* HAMBURG REMARKS], Oct. 8, 2010, at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf>.

⁴⁰ Connie T. Jung, *Counterfeit Drugs and Drug Importation: Role of FDA*, U.S. Food and Drug Administration, USPHS Scientific and Training Symposium June 2, 2009 at <http://www.phscof.org/events/sym09/Tuesday/A602/Jung.pdf>.

⁴¹ Rajendrani Mukhopadhyay, *The Hunt for Counterfeit Medicine*, 79(7) ANALYTICAL CHEMISTRY 2622 (2007).

⁴² M. Paxton, *Current Challenges With Supply-Chain Integrity and the Threat to the Quality of Marketed Drugs*, 89(2) CLINICAL PHARMACOLOGY & THERAPEUTICS 316 (2011), at <http://www.nature.com.ezp-prod1.hul.harvard.edu/clpt/journal/v89/n2/full/clpt2010288a.html>.

⁴³ Roger Bate & Karen Porter, *Regulation in the Era of Globalization*, J. OF THE AMERICAN ENTERPRISE INSTITUTE, February 27, 2009, at <http://www.american.com/archive/2009/february-2009/regulation-in-the-era-of-globalization>

⁴⁴ Jung, *supra* note 28.

⁴⁵ Paxton, *supra* note 30, at 316.

channels of drug distribution and venture into the online world for their drugs. Thus, even if the percentages in the US are small and the FDA is vigilant in trying to prevent the risks, just one infiltration of a harmful ingredient can lead to devastating consequences.⁴⁶ In addition, the FDA is not only a crisis responder, importantly, it is tasked with “preventing problems before they occur.”⁴⁷

B. *The Reimportation Debate*

As imported drugs and online pharmacies raised the worry over counterfeit medicine, they have also brought to the forefront the debate on drug reimportation. The issues are similar and the safety concerns overlap. The difference with reimportation is that the drugs have actually been manufactured in the US, exported to other countries, and then reimported back into the US.⁴⁸ The concerns that Congress has cited in the past over this practice include the fact that once the drugs leave the country, US has no control in how the drugs are stored and handled and also, that allowing reimportation would encourage counterfeiters to import the drugs “under the guise of a reimported pharmaceutical.”⁴⁹ Supporters of pharmacies and research companies echo the safety arguments, and also decry the chilling effect both importation and reimportation would have on research and development (R&D), because companies would not be able to “recover the costs required for the new drug discovery,” and

⁴⁶ See e.g. Bate & Porter, *supra* note 43, stating how the “deaths of 95 Americans” were “tied to contaminated heparin, a blood-thinning medication imported from China.”

⁴⁷ HAMBURG REMARKS, *supra* note 39.

⁴⁸ See Choudhry & Detsky, *supra* note 4, at 358.

⁴⁹ Palumbo et al. *supra* note 28, at 2759.

profits available for future R&D would be reduced.⁵⁰ The director of the American Council on Science and Health, emphasizes that “allowing price controls into this country is a sure path to destroying our drug industry, which is now a prime driver in developing new and innovative pharmaceuticals.”⁵¹ In addition, the CEO of the Healthcare Distribution Management Association, John Gray, had this to say in response to Senator Dorgan’s proposal regarding allowing the importation of prescription drugs (to be discussed in Part IV of this paper):

“Importation of prescription drugs from foreign countries, as Sen. Dorgan and others propose to allow, would compromise the secure U.S. distribution system by increasing the likelihood of entry for counterfeit or adulterated medicines . . . [e]fforts to sell counterfeit or adulterated medications produced overseas have become far more sophisticated in just the past few years.”⁵²

What complicates the issue, as mentioned previously, is consumer demand for cheaper medicine. Many are skeptical of warnings and outcries by the pharmaceutical industry, arguing that the exaggerated safety concerns are just a way for the industry to keep prices unfairly high, at the expense of patients.⁵³ There are two main questions to grapple with: 1) are the safety concerns really exaggerated and are patients getting good medicine through reimportation? 2) would legalized reimportation save money?

⁵⁰ Bhosle & Balkrishnan, *supra* note 2, at 43.

⁵¹ Gilbert Ross, *Why Drug 'Reimportation' Won't Die*, WALL ST. J., Jan. 7, 2010.

⁵² Alaric DeArment, *HDMA criticizes personal drug importation amendment in healthcare-reform bill*, Drug Store News, Dec. 8, 2009, at <http://www.drugstorenews.com/article/hdma-criticizes-personal-drug-importation-amendment-healthcare-reform-bill>.

⁵³ Jeffrey Young, *FDA opposes Senate drug importation amendment offered to healthcare bill*, Dec. 8, 2009, The Hill, at <http://thehill.com/homenews/senate/71307-fda-opposes-senate-drug-importation-amendmen>. Quoting Senator Dorgan that “U.S. consumers are charged the highest prices in the world for FDA-approved prescription drugs, and that’s just not fair.”

Despite the statistics and warnings cited in the importation part of this paper, some argue that the threat is exaggerated. For instance, in a study published in 2010, the researchers looked at the quality of five different drugs (Lipitor, Viagra, Celebrex, Nexium, and Zoloft), purchased from seventy different online pharmacies. According to their conclusions, all the drugs passed “basic quality testing.”⁵⁴ While this may seem encouraging, this study is not particularly persuasive – because of the small sample size of both the pharmacies and the drugs studied (a fact that the researcher himself acknowledges).⁵⁵ Also, there are FDA investigations which show a less optimistic view of internet ordering. When FDA examined 4,000 mail parcels at an airport, it found that forty-three percent were ordered from Canadian internet pharmacies but only fifteen percent actually were from Canada, and thirty-two of the drugs sampled were counterfeit.⁵⁶ Counterfeit or substandard drugs may not be a problem in the US to the same degree as in some other countries, but they are a real and growing threat. While it is true that reimported drugs (if they are truly reimported and not just labeled so), have been manufactured under the strict US standards, once they leave the US, there are a number of points at which the drug may become unsafe. As a former Chief of Counsel for the FDA stated in 2002, “[d]rugs are highly sensitive and can become adulterated and dangerous during shipping

⁵⁴ See Roger Bate, *Republicans Risk Alienating the Elderly and Poor by Pursuing a Conflicted Strategy on Drug Importation*, American Enterprise Institute for Public Policy Research, December 13, 2010, at <http://www.aei.org/article/102892>; and Roger Bate & Kimberly Hess, *Assessing Website Pharmacy Drug Quality: Safer Than You Think?*, 5(8) PLoS ONE, (2010), at <http://www.plosone.org/article/info:doi/10.1371/journal.pone.0012199>.

⁵⁵ See Bate, *supra* note 52.

⁵⁶ *FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries*, FDA News Release, Dec. 16, 2005, at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108534.htm>.

if not properly controlled and monitored.”⁵⁷ In addition, he pointed out the numerous aspects of drug manufacturing and processing that the FDA must monitor to ensure a safe drug supply, including personnel, equipment, and product design, and which is difficult to do effectively when the drug is coming from another country.⁵⁸

The other part of the debate concerns the question of pricing. Since countries such as Canada have drug price control acts, consumers reimporting medicine save money by buying at capped prices.⁵⁹ There are studies estimating that consumers save between “20%–80% on brand name drugs,” but some argue that the estimates are “overestimated considering the complications involved in comparing medication prices across different nations.”⁶⁰ The problems cited with price comparisons across nations include finding drugs to compare across countries, matching the drug specifications, and “incorporating variables such as discounts and rebates” as well as “accounting for differences in drug consumption patterns, and accounting for differences in purchasing power across countries.”⁶¹ In addition, in a study comparing prices of US drugs to other countries, researchers found that the “overall price variations were not as large as widely perceived because price differentials were generally related to the income differences between each country.”⁶² Thus, even the argument that reimportation saves money despite the risks, may not hold as much water at a closer look.

⁵⁷ Peter Hutt, Examining Prescription Drug Reimportation: a Review of a Proposal to Allow Third Parties to Reimport Prescription Drugs, Statement to Subcommittee on Health, July 25, 2002, at <http://republicans.energycommerce.house.gov/107/hearings/07252002Hearing677/Hutt1150.htm>.

⁵⁸ *See id.*

⁵⁹ *See* Bhosle & Balkrishnan, *supra* note 2, at 42. A popular HIV drug (Ritonavir) costs \$700/per year in Canada compared to \$7800/per year in the US.

⁶⁰ *Id.* at 41.

⁶¹ Palumbo et al., *supra* note 28, at 2760.

⁶² *Id.*

On the other hand, despite the difficulty in comparative and policy analysis of prices and economic theorizing, if a chronically ill patient sees a difference in his bank account when he purchases medicine from an online pharmacy, it becomes harder to argue that the price saving is illusory at the individual consumer level.

Finally, despite the prevalence of the view that both importation and reimportation are a way to cut healthcare costs and increase affordability, not everyone agrees. The Department of Health and Human Services, for instance, in its 2005 Report on Importation, concluded that national savings from importation would be a “small percentage of total drug spending,” and that developing the program, along with the safeguards needed to reduce risk, would actually “increase the costs of imported drugs.”⁶³ In addition, it argued that the prices that foreign consumers pay are “on average 50 percent greater than prices Americans pay for generic drugs,” and thus the “public expectation that most imported drugs are less expensive than American drugs is not generally true.”⁶⁴ The arguments are echoed by the FDA, which has stated that consumers do not need to buy prescription drugs from foreign sources on the Internet because “low-cost generic versions are available in the United States.”⁶⁵

IV. Response and Regulation

There is tension between the FDA and other agencies working to assure drug safety and those that seek to implement an importation program for consumers. In addition to the

⁶³ Report of the HHS Task Force on Drug Importation, Statement by Richard H. Carmona, U.S. Public Health Service Department of Health and Human Services, before the Special Committee on Aging, United States Senate [*hereinafter* HHS TASK FORCE STATEMENT], Jan. 26, 2005, at <http://www.hhs.gov/asl/testify/t050126.html>.

⁶⁴ *Id.*

⁶⁵ FDA News Release, July 2, 2007, *supra* note 1.

enacted legislation, there have been and are bills introduced in an attempt to create an importation program.⁶⁶ The regulations that exist right now do provide the tools to handle the rising safety threats, but there are still many concerns about their effectiveness as counterfeiters adapt and learn to bypass these safeguards, especially on the internet, and as consumer demand for cheaper medicine rises, which drives political pressure to relax importation and reimportation standards.

Under the Federal Food Drug & Cosmetic Act (FDCA), it is illegal to ship in interstate commerce and import unapproved drugs.⁶⁷ The FDA pointed out that in certain limited circumstances, importation for individual use may be allowed.⁶⁸ It also warned, however, that the listed exceptions are not “a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S., and even if all the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized.”⁶⁹ Consumers have not heeded these warnings. FDA’s personal use policy was meant for patients who could not otherwise get the drugs in the US, but it has been “institutionalized to the point where any consumer can bring into the country any prescription drug in any quantity for an indefinite period of time.”⁷⁰ Part of the problem is probably confusion about the legality of buying online, but part of it is probably the belief that FDA will not go after individuals buying small amounts of medicine.

⁶⁶ See e.g. Safe Import Act of 2005, S. 184, 109th Cong.; Pharmaceutical Market Access and Drug Safety Act of 2007, S. 242, 110th Cong.

⁶⁷ See Information on Importation of Drugs Prepared by the Division of Import Operations and Policy [*hereinafter* INFORMATION ON IMPORTATION], FDA Industry Guide, updated June 30, 2010, at <http://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm>; and 21 U.S.C. § 331.

⁶⁸ *Id*; Coverage of Personal Importations, Regulatory Procedures Manual, updated Feb. 16, 2010, at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm>

⁶⁹ INFORMATION ON IMPORTATION, *supra* note 65.

⁷⁰ Palumbo et al., *supra* note 28, at 2759.

Reimportation is also illegal in most circumstances. In response to two major incidents that occurred in the 1980s –unsafe birth control pills (Ovulent-21) from Panama and a counterfeit antibiotic (Ceclor) that were introduced into the US market, the FDCA was amended by the Prescription Drug Marketing Act of 1987 (PDMA).⁷¹ The PDMA was enacted to “ensure the safety and effectiveness of prescription drug products and to safeguard the American public from the risk of counterfeit, adulterated, misbranded, sub-potent, or expired drugs.”⁷² The Act makes it “illegal for anyone other than the drug’s original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S.”⁷³ The Act provides, however, that the “FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.”⁷⁴ The Act was further modified by the Prescription Drug Amendments of 1992.⁷⁵ In addition to the reimportation prohibition, the PDMA established “pedigree requirements,” which means drugs have to be accompanied with a “statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them.”⁷⁶

⁷¹ See Counterfeit Drug Task Force Report - Background: Vulnerabilities in the U.S. Drug Distribution System, October 2003, at <http://www.fda.gov/Drugs/DrugSafety/ucm174479.htm>; Pub. L. No. 100-293, *codified* 21 U.S.C. § 381.

⁷² Counterfeit Drugs, Statement of Randall W. Lutter before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources House Committee on Government Reform, Nov. 1, 2005, at <http://www.fda.gov/newsevents/testimony/ucm112670.htm>.

⁷³ TAYLOR STATEMENT, *supra* note 16.

at <http://www.fda.gov/newsevents/testimony/ucm113635.htm>.

⁷⁴ 21 CFR § 203, at http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr203_02.html.

⁷⁵ Pub. L. No. 102-353, *codified* 21 U.S.C. § 381.

⁷⁶ *Id.*, see also CPG Sec. 160.900 Prescription Drug Marketing Act - Pedigree Requirements under 21 CFR Part 203, FDA Compliance Policy Guide, Revised Dec. 23, 2010 at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073857.htm>, explaining that while the pedigree requirements have been delayed, they will be enforced.

In 2000, the Medicine Equity and Drug Safety Act (MEDSA) was enacted which “expanded the reimportation provisions by allowing pharmacists and wholesalers to be additional reimporters” but only with the approval of the Secretary of Health and Human Services, which did not occur.⁷⁷ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) also authorized “a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply,” and also asked for a “comprehensive study” and a report “on whether and how importation could be accomplished in a manner that assures safety.”⁷⁸ In addition, the Act provided that the Secretary may “grant a waiver by regulation or on a case-by-case basis of the existing prohibition to personal importation.”⁷⁹ In 2004, HHS created a task force “charged with gathering input, ideas, and expertise from the public on issues related to drug importation.”⁸⁰ Among its numerous conclusions, the Task Force found that there are “significant risks associated with the way individuals are currently importing drugs that violate” the FDCA, that there are threats to the US drug supply, and that “[i]t would be extraordinarily difficult and costly for “personal” importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.”⁸¹ Thus, the HHS Secretary has not granted importation permissions, FDA has

⁷⁷ Palumbo et al., *supra* note 28, at 2763; Pub. L. No. 106-387, *codified* 21 U.S.C. § 333, 381, 384.

⁷⁸ TAYLOR STATEMENT, *supra* note 16; Pub. L. No. 106-387, *codified* 21 U.S.C. § 333, 381, 384.

⁷⁹ Palumbo et al., *supra* note 28, at 2763.

⁸⁰ HHS TASK FORCE STATEMENT, *supra* note 61.

⁸¹ *Id.*

opposed importation in violation of FDCA provisions, and protests against the Secretary's and the Agency's discretion have been unsuccessful.⁸²

FDA got a boost to its authority when Congress passed the Food and Drug Administration Amendments Act of 2007, which among other issues, addresses pharmaceutical safety.⁸³ The Act provides that "the Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs."⁸⁴ The standards include those for "identification, validation, authentication, and tracking and tracing of prescription drugs," and among the technologies mentioned to achieve these goals are radio frequency identification technology (RFID) and encryption.⁸⁵ The Act also calls for expansion of agency resources and for collaboration to enhance "regulatory and criminal enforcement" of the Act and to "secure the drug supply."⁸⁶

In 2009, importation was back on the front scenes with a proposal to "legalize the importation of medicines at lower, government-regulated prices from Canada and other countries," under the Patient Protection and Affordable Care Act.⁸⁷ The proposal was introduced by Senator Byron Dorgan as an amendment to the Act.⁸⁸ The FDA opposed it, citing

⁸² See e.g. *United States v. Rx Depot, Inc.*, 438 F.3d 1052 (10th Cir. 2006).

⁸³ Pub. L. No. 110-85, one of the stated purpose of the Act is to "enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs;" available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.

⁸⁴ *Id.*, § 913.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ Ian D. Spatz, *Health Reform Accelerates Changes In The Pharmaceutical Industry*, HEALTH AFFAIRS 30(3) 1331, 1332 (2010).

⁸⁸ See Alicia Mundy, *Dorgan and McCain: Live in Concert! One Day Only!*, WALL ST. J HEALTH BLOG, Dec. 9, 2009, at <http://blogs.wsj.com/health/2009/12/09/dorgan-and-mccain-live-in-concert-one-day-only/>.

safety and implementation concerns.⁸⁹ The amendment failed in the Senate.⁹⁰ The White House issued a statement that the administration “supports reimportation of safe and effective drugs,” but that the FDA “has raised safety concerns about the current proposal and will continue exploring policy options to create a pathway to importing safe and effective drugs.”⁹¹ Recently, in February 2011, the President was quoted as saying that importation is “still something we should look at in terms of further lowering the price of drugs,” in response to a consumer question.⁹² The debate seems far from over.

Another issue is the response of states to consumer concerns over high prices and access to drugs. Numerous states have had initiatives to facilitate drug importation for its residents, especially from Canada. Some examples of the initiatives include Springfield, Massachusetts, which “engaged the services of CanaRx to facilitate the first effort to formalize obtaining drugs from Canada;” Illinois establishing the “I-SaveRx” program, allowing importation with some additional safeguards, a move followed by Wisconsin, Kansas, Vermont, and Missouri; and in 2005, “Maine, Nevada, Texas, Vermont, and Washington passing legislation to help facilitate the importation of Canadian drugs by their residents.”⁹³ The FDA

⁸⁹ See Alicia Mundy, *FDA Questions Reimportation of Drugs*, WALL ST. J., Dec. 9, 2009.

⁹⁰ *Senator Dorgan Proposes Drug Importation One Last Time; Limited Personal Drug Importation Bill Might Prove More Workable*, Online Pharmacy and Prescription Drug Review, published by PharmacyChecker.com, at <http://pharmacycheckerblog.com/senator-dorgan-proposes-drug-importation-one-last-time-limited-personal-drug-importation-bill-might-prove-more-workable> (accessed March 13, 2010).

⁹¹ Stephanie Condon, *Health Care Bill Brings Debate Over Importing Drugs*, CBS News, Dec. 11, 2009, at http://www.cbsnews.com/8301-503544_162-5967799-503544.html.

⁹² *Obama Interview Shows Americans Highly Concerned About Drug Prices; Drug Importation Mentioned as Potential Solution*, Online Pharmacy and Prescription Drug Review, published by PharmacyChecker.com, at <http://pharmacycheckerblog.com/obama-interview-shows-americans-highly-concerned-about-drug-prices-drug-importation-mentioned-as-potential-solution#more-1061> (accessed March 13, 2010).

⁹³ Palumbo et al., *supra* note 28, at 2761.

has taken action against some of these programs, by issuing warning letters to companies such as CanaRx.⁹⁴

V. Future Solutions

Despite some of the numbers cited earlier, the first problem with addressing importation is that there are not enough comprehensive and independent studies to provide information for policy makers to make decisions. For instance, it is still unclear exactly how many counterfeit drugs make their way into the US.⁹⁵ Thus, the first possible solution to the issues raised in this paper, is for the government to encourage research on the prevalence of counterfeit drugs in the US, isolate their sources, and quantify which sources (e.g. online pharmacies) pose the greatest threat.

Next, it is important to realize that consumer demand for buying drugs online is robust, and as the demand increases, the potential danger for counterfeit products making their way into the US also increases. It would be an impossible task to try and close down every illegal drug site. Thus, consumers need to be educated about online drug risks and discouraged from buying from suspicious pharmacies. This is difficult to do, especially when many do not see anything wrong with importation (and some think it is perfectly legal), and also see federal agencies as working on the side of pharmaceutical companies to keep drug prices high. One

⁹⁴ See *id.*

⁹⁵ See Facundo M. Fernandez, Michael D. Green, and Paul N. Newton. *Prevalence and Detection of Counterfeit Pharmaceuticals: A Mini Review*, 47 IND. ENG. CHEM. RES. 585 (2008), noting that a “common obstacle in the fight against drug counterfeiting refers to the lack of robust information regarding the prevalence of fake drugs, globally or in any country. Sadly, there are no accurate statistics representative of the extent of the problem, partly due to lack of sufficient resources and poor reporting practices.”

solution would be to cooperate with consumer advocate groups to find a middle-ground for enforcement. However, the government has to be careful not to send the wrong message to online shoppers. One commentator suggests, for instance, to decriminalize personal importation of drugs for up to a ninety day supply, but continue to “deny insurance reimbursement for such purchases,” as a way to “assist the poorest” while not undermining “tiered pricing on which future drug and research development depends.”⁹⁶ Such a measure may actually have a very damaging effect. As mentioned previously, consumers already took a small exception regarding personal exemptions and flocked with it to internet pharmacies, it may be that an outright decriminalization of importation, even if only for a small supply, will simply encourage such behavior more and possibly make shoppers less careful, making them interpret decriminalization as government admission that the threat is exaggerated. Despite the necessary balancing, the FDA’s priority should still be safety.

The next solution then, is to address consumer concerns about drug pricing. This has already been done to some extent with the enactment of Medicare Part D, which “has taken some of the pressure from pricing issues for many elderly US patients.”⁹⁷ However, many people still cannot afford medicine, or visits to the doctor’s office for a prescription. It is up to the government to look at a deeper level at the nature of US healthcare to seek solutions. The FDA should not have to back down from its stance that unapproved medicine from other countries is dangerous. Also, some consumers, as the FDA suspects, purchase drugs online not because they are cheaper, but because they want to avoid getting a prescription.⁹⁸ Stricter

⁹⁶ Bate, *supra* note 52.

⁹⁷ Palumbo et al., *supra* note 28, at 2764.

⁹⁸ See FDA News Release, July 2, 2007, *supra* note 1.

enforcement needs to happen against sites selling unapproved drugs without a prescription, and maybe even penalties for consumers who continue to do this. In addition, more studies about consumer behavior and attitudes toward online purchasing would help in understanding how to combat the problem.

Finally, the FDA and other agencies have been on the right track in terms of trying to incorporate new technologies to combat counterfeiting and other online pharmacy risks. However, more resources and effort need to be allocated to implement these technologies. One of the promising ways to make sure that limited resources are being allocated properly and effectively, is developing risk assessment strategies, which means prioritizing areas that are deemed to be the most vulnerable to safety concerns, and this is also a step that FDA has recognized as important.⁹⁹

It seems hard to reconcile opposing views on these issues, but that is because proponents and the federal government often speak at cross-purposes. If the public keeps being educated about the concerns, and sees that steps are being taken to address the demand for cheaper prices, it will be more likely to recognize that the safety risks are not exaggerated.

VI. Conclusion

In the end, online drug shopping is not the end of times as it may have seemed to some when patients first found their way onto the internet. There are many advantages to providing people with more efficient and easier ways to purchase medicine. However, as with any new technological development, there are wrongdoers who will try to profit by finding loopholes

⁹⁹ HAMBURG REMARKS, *supra* note 39.

while the regulatory system catches up. It is important for FDA and the government to remain committed to protecting consumers and educating them about the risks of online drug shopping, to keep online pharmacies limited to only the ones that sell FDA-approved drugs, and to go after illegal importation and reimportation. The debate will continue, and something does need to be done when people cannot afford their medicine, but lowering safeguards that currently protect patients is not the solution.